Jonathan's ORGANIC

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11/8/99

To whom it may concern:

Regarding the recently released sprout "Guidance for Industry" document, I would like to point out several negative effects if the guidances become FDA requirements for commercial sprout-growing, one of which might preclude the use of the proposed testing protocols altogether. I would also like to suggest an alternative which might provide adequate risk reduction, without the negative consequences.

One problem with the implementation of the testing as described is that if presumptive positives occur with any frequency, the ability of the grower to run an effective business and to supply his markets at the required level of consistency will be out of the question. Aside from the logistical confusion of how to manage a portion of a crop which has given a presumptive positive, and the crisis in customer confidence when part of a shipment is withheld because of questions about its safety, there is the predicament of what the grower is supposed to do with the remainder of the seed of the lot in question, even if the presumptive positive turns out to be false. Is he to plant the same seed again, and again get a presumptive positive, and again hold everything up? Can he assume that the second presumptive positive is merely a repeat of the first, and can be ignored? No; it seems obvious that any seed which gives a presumptive positive will have to be gotten rid of.

A related problem is: if a grower uses a seed for some time without getting any presumptive positives, and then gets one, what is he to conclude about product from the same seed lot he has already shipped?

Again, unless presumptive positives are extremely rare- and the evidence seems to be that they are not rare- the logistics of running a sprout business will become next to impossible.

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Even if false positives are very rare, one consequence of the guidelines will be the dismantling of the sprout industry as a collection of mostly small, independent entrepreneurs, and its replacement by a few highly capitalized and centralized producers. This is because the FDA guidance requirements are inherently too expensive for a small grower.

The problems and health hazards of implementing strong chlorine soaks are already familiar to many growers.

Another negative consequence is the complete elimination of the organic sprout industry, and the setting of a regulatory precedent which inherently invalidates several premises of organic food production.

If presumptives are very rare, the guidelines will make it easier for a large producer or seed supplier, not involved with organic production methods, and either large enough to set up an in-house testing facility, or to maintain a continuous relationship with an outside lab, to take over markets presently served by small growers, even if these small growers have for years provided excellent service to their customers.

These negative consequences would seem to be inevitable under the present "Guidelines." The only question is whether they are necessary or desirable.

An alternative which could avoid all these negative consequences is a pre-production seed sampling and testing protocol designed specifically for sprouting seed.

The FDA and CDC research indicates that all the problems associated with sprouts in the last several years, with the possible exception of a single one, have been caused by pathogens entering the sprouting facility on the seed.

It is also acknowledged that growing contaminated seed in a facility with the most sophisticated equipment and environmental controls, and flawless GMP's will not diminish the likelihood of shipping contaminated product, if the seed is contaminated.

It is recognized by the FDA that there is no presently known, reliable way to disinfect contaminated seed. Conversely, there is no evidence that sprout-growers, using reasonable care and common sense, and their own ingenuity, cannot produce safe sprouts if the seed they are using does not contain pathogens.

So, empirically, the problem could be said to be the elimination of contaminated seed from sprout-growing facilities. So far, almost all of the research inquiry into sprout safety has been based on the assumption that preventing contaminated seed from entering the sprouting facility in the first place is either impossible, or impractical.

The major seed suppliers have until recently maintained that any control over the microbial or physical characteristics of their seed was either impossible or impractical,

and that all safety measures should therefore be the responsibility of the grower. For this reason, there has not been any thorough discussion of what might be involved to provide safe seed for the sprouting industry.

Lately, several seed suppliers have introduced methods of seed sampling and testing for their sprouting seed. One hears various things about the kinds of sampling and testing which are being done, such as "by FDA-approved sampling methods" - but existing sampling and testing methods for other types of seed are probably not adequate for significant risk-reduction on sprouting seed.

One problem with seed sampling is that it must be based on an assumed minimum level of contamination. Since this level can never be known for a certainty, it is argued that seed sampling is inherently unreliable.

The level of pathogens found in naturally contaminated seed which has been obtained by researchers is estimated (in the NACMCF White Paper) to be as low as 4 CFU per kilo. The White Paper seems to conclude that such low levels preclude effective sampling. However, an entirely feasible sampling and testing of these observed lots of seed prior to their use in production could have averted the outbreaks which they caused.

A contamination level of 4 CFU per kilo, even if all CFU happened to originate on a single seed in each kilo, could be detected to a 99.99 % probability by taking a 10 kilo random sample from the seed lot in question, growing it out, and testing the runoff from the resulting sprouts.

A formula for determining probabilities of detecting pathogens in samples of various sizes can be expressed as P = 1-C/T^N, where P is the probability of detection, C/T is an estimated ratio of clean seed to total seed, and N is the number of seeds sampled. Attached to this letter is a chart based on this formula, showing detection probabilities for various sample sizes and contamination levels. It suggests that with adequate sampling methods and sample sizes, very high probabilities of detection can be attained for contamination levels well below anything yet observed.

Although taking a 10 kilo, or even a 100 kilo, random sample, and then growing the sample and testing the resulting sprouts, may seem impractical, it is not nearly so difficult, expensive, and dangerous as the presently recommended chlorine treatment, and it would avoid the pitfalls of the testing recommended in the guidelines.

Large-scale sampling and testing of sprouting seed prior to arrival at the individual sprouting facility could allow small producers to stay in business, and would also allow the organic sprout industry to survive. It would involve a simple apparatus to be installed on any bagging equipment which was processing seed intended for sprouting. The accompanying drawing shows one possible configuration.

The apparatus would have to be sanitized prior to use on any lot of seed. As the seed

is poured through the device, a baffle located inside the tube causes the seed to bounce, and a certain amount bounces out the hole in the side. This would comprise the sample. The amount of seed sampled could be set by adjusting the location of the baffle relative to the hole.

As opposed to most seed-sampling methods, such a sampling device would prevent missing localized contamination in a bag of seed. A ten kilo sample taken from 10,000 pounds of seed would sample an average of five hundred random locations in each pound of seed, or about one location per cc. The amount of seed used in a ten kilo sampling of a 10,000 lb seed lot would be 2/10 of 1%. Even a 50 kilo sample taken this way would use only 1% of the seed, and could provide a 99.9999%+ probability of detection of a contamination level of 1 CFU per KG, lower than anything yet observed in naturally contaminated seed.

The seed from any single application of the sampling device would have to be bagged in contamination-proof bags, tagged; and stored in a separate location until the seed had been grown out and thoroughly tested. The sprouts grown from the sample could be composted, or used for purposes other than human consumption. There would be no urgent deadline or need for presumptive testing.

If the sample gave positives for any pathogens, the seed would be disqualified as a sprouting seed, and sold for other purposes. If it was found acceptable, it could be certified according to the specific testing done. The integrity of the bags between sampling and end use could be determined by black-light inspection of the bags at the sprouting facility.

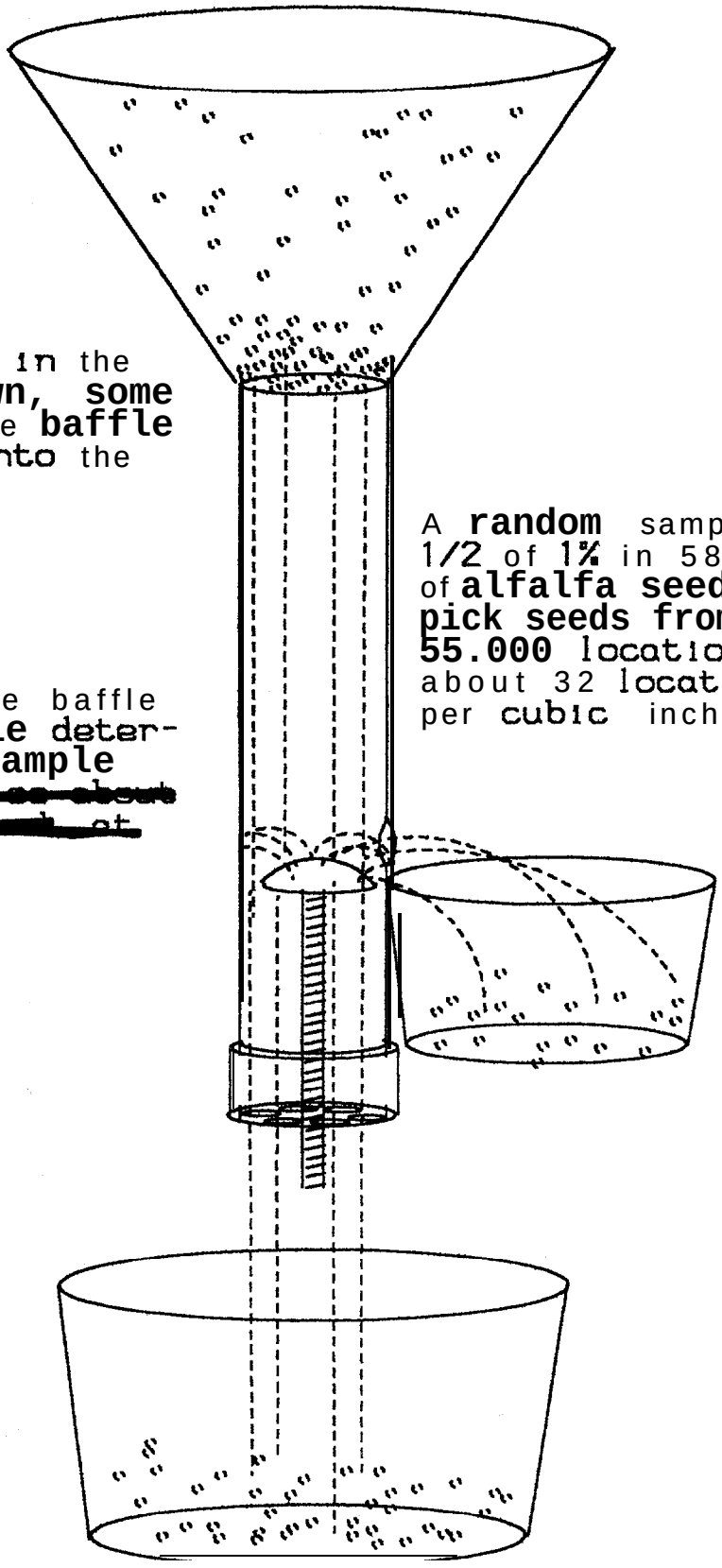
Thorough pre-production seed sampling and testing could preserve the sprouting industry as a unique community of inventive entrepreneurs, and would be entirely compatible with organic production requirements. It would avoid the many potential problems associated with chemical treatments, such as disposal problems, worker health problems, as well as the possibility of selecting for resistance, and increased susceptibility to contamination through elimination of background flora.

Jonathan Sprouts, for itself and on behalf of the sprout industry, and the organic industry, ask that the FDA give this proposal its serious consideration as an alternative to the recently published guidelines. We are presently involved in the development of effective sampling and testing protocols, and would like very much to work with the FDA or any other organizations to assist in the rapid evolution of safe, effective sprouting practices.

Yours-truly,

Bob Sanderson
President
Jonathan Sprouts, Inc.

SEED SAMPLER
(Can be constructed in any size)



The seed is poured in the top. As it **falls down, some seed** bounces off the **baffle and out** the hole into the **sampl** rng cup.

The position of the baffle **relative to** the **hole** determines **how big** the **sample** is. [redacted]

A **random** sampling of 1/2 of 1% in 58 **lbs** of **alfalfa seed would pick seeds from about 55.000** locations, or about 32 locations per cubic inch.

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